Complete Summary

GUIDELINE TITLE

Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. 37 p. (Technology appraisal guidance; no. 112).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Early oestrogen-receptor-positive breast cancer

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Oncology

INTENDED USERS

Advanced Practice Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical and cost effectiveness of hormonal therapies (anastrozole, letrozole, exemestane) for the adjuvant treatment of early oestrogen-receptor-positive breast cancer

TARGET POPULATION

Postmenopausal women with early oestrogen-receptor-positive invasive breast cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Aromatase inhibitors, including anastrozole, exemestane, and letrozole

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
    - Over-all survival
    - Disease-free survival (DFS)
    - Recurrence
    - Health-related quality of life
    - Adverse events and toxicity
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield (See the "Availability of Companion Documents" field.)

Clinical Effectiveness

Search Strategy

The search aimed to identify all studies relating to anastrozole, letrozole and exemestane for the treatment of early stage breast cancer. The following databases were searched: Medline, the Excerpta Medica Database (EMBASE), Cumulative Index of Nursing and Allied Health Literature (CINAHL), Biosciences Information Service (BIOSIS), the Cochrane Database of Systematic Reviews, the Cochrane Controlled Trials Register, the Science Citation Index and the National Health Service (NHS) Centre for Reviews and Dissemination databases (Database of Abstracts of Reviews of Effectiveness [DARE], National Health Service Economic Evaluation Database [NHS EED], HTA) and OHE Health Economic Evaluations Database (HEED). Pre-Medline was also searched to identify any studies not yet indexed on Medline. Current research was identified through searching the National Research Register, the Current Controlled Trials register, the Medical Research Council Clinical Trials Register and the proceedings of the American Society for Clinical Oncology (ASCO), the European Society for Medical Oncology (ESMO) and the San Antonio Breast Cancer Symposium (SABCS). Any industry submissions, as well as any relevant systematic reviews were hand-searched in order to identify any further clinical trials. Searches were not restricted by language, date or publication type. The MEDLINE search strategy is presented in Appendix 2 of the Assessment Report (see the "Availability of Companion Documents" field).

Inclusion and Exclusion Criteria

Systematic reviews and Phase III randomised controlled trials were included. Reviews of primary studies were not included in the analysis. Studies which were considered methodologically unsound were excluded from the review.

Studies randomising only the following population groups were included: postmenopausal women who have had surgery for early stage breast cancer (stages I and II of the American Joint Committee of Cancer [AJCC] system), whose tumours are oestrogen-receptor positive and: (a) who are hormonal therapy-naïve; (b) who have survived disease-free after two to three years of tamoxifen; or, (c) who have survived disease-free after five years of adjuvant tamoxifen. Studies designed to evaluate the experimental interventions in the following population groups were excluded: men; pre-menopausal women, women with ductal carcinoma *in situ*, advanced stage breast cancer or oestrogen receptor negative tumours.

Studies randomising only to the following experimental interventions were included: any one of the following aromatase inhibitors: anastrozole, letrozole, or exemestane, administered adjuvant to surgical resection. This review considers any treatment strategy containing one of the above aromatase inhibitors, regardless of the point of randomisation in the study or the length and structure of the treatment programme. Studies randomising to the following interventions were excluded: aromatase inhibitors administered as neoadjuvant treatment; aromatase inhibitors administered in the adjuvant setting where the women in the comparator arm are not offered the current standard treatment of five years' single agent tamoxifen (regardless of the point of randomisation).

Studies randomising only to the following comparators were included: tamoxifen alone, where trials randomise women who are hormonal therapy-naïve or have survived disease-free after two to three years of tamoxifen; placebo, where trials randomise women who have survived disease-free after five years of adjuvant tamoxifen. Studies randomising to other comparators were excluded.

Studies designed to assess the following outcomes were included: overall survival (the review's primary outcome), defined as the hazard of death from any cause after any follow-up, or the time to death from any cause expressed in months; disease-free survival however defined; recurrence, however defined; adverse events and toxicity however defined; and, health-related quality-of-life, however defined.

Where outcome data was available the following subgroups were analysed separately: node positive versus node negative tumours; expression of other molecular markers where available.

Economic Analysis

Identification of Studies

The aim of the search was to provide as comprehensive a retrieval as possible of economic evaluations of the hormonal therapies - anastrozole, letrozole and exemestane in the treatment of early breast cancer.

Sources Searched

Eight electronic databases were searched providing coverage of the biomedical and health technology assessment literature (BIOSIS, CINAHL, EMBASE, OHE HEED, HTA, Medline and PreMedline, and the NHS EED). The ASCO and ESMO conference abstracts and two current research registers (Current Controlled Trials and National Research Register) were also searched. The websites of the following organizations were also searched The Agency for Healthcare Research and Quality (AHRQ), Canadian Coordinating Office for Health Technology Assessment (CCOHTA), eMC, European Agency for the Evaluation of Medicinal Products (EMEA), International Network of Agencies for Health Technology Assessment (INAHTA) Clearinghouse, National Guidelines Clearinghouse, The National Coordinating Centre for Health Technology Assessment (NCCHTA) and The Scottish Intercollegiate Guidelines Network (SIGN). The economic assessments submitted by sponsors were identified as studies for inclusion in the review. In addition, the sponsor submissions were hand-searched for further references to studies.

Keyword Strategies

The keyword strategies developed in the review of clinical effectiveness were used, with the randomized controlled trial (RCT) methodological filter being replaced by a filter aimed at restricting search results to economic and cost related studies. An example search strategy for the Medline database is provided in Appendix 2 of the Assessment Report (see "Availability of Companion Documents" field).

Search Restrictions

The same limits and restrictions used in the review of clinical effectiveness were applied with the exception of the methodological filter as described above. All searches were undertaken in June 2005.

Inclusion and Exclusion Strategy

Studies were selected for inclusion according to pre-determined inclusion and exclusion criteria. Studies were included if they reported the cost-effectiveness of aromatase inhibitors in the adjuvant treatment of early breast cancer. Studies which were considered to be methodologically unsound, that were not reported in sufficient detail or that did not report an estimate of costs-effectiveness (e.g., costing studies) were excluded.

Two reviewers independently screened all titles and abstracts. Disagreement was settled through discussion. Full paper manuscripts were obtained for any titles/abstracts that were considered relevant or where the title/abstract information was not sufficient to make a decision.

Reviews discussing cost-effectiveness studies of aromatase inhibitors were not included in this review but were retained for use in discussion.

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

One hundred and three citations pertaining to seven prospective randomized controlled trials and two secondary studies met the inclusion criteria.

Cost Effectiveness

Only one full study satisfied all inclusion and exclusion criteria and formed the basis of the review.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield (See the "Availability of Companion Documents" field.)

Clinical Effectiveness

Validity Assessment

Published papers were assessed according to the accepted hierarchy of evidence, whereby meta-analyses of randomised controlled trials are taken to be the most authoritative forms of evidence, with uncontrolled observational studies the least authoritative.

Two researchers assessed papers, unblinded, for four generic dimensions of methodological quality associated with estimates of treatment effects in controlled trials: (1) allocation concealment; (2) randomization method; (3) intention-to-treat analysis; and, (4) double-blinding. The quality of reporting in studies assessing quality of life endpoints was also critically appraised.

The purpose of these assessments was to give a narrative assessment of the potential for bias in the studies and, in the event that statistical synthesis (meta-analysis) was appropriate, to inform sensitivity analysis: poor reporting in trial reports is linked with a lack of clarity in protocols, which is in turn linked with exaggeration of the treatment effect.

Data Abstraction

The most complete dataset feasible was assembled. Where the team was aware that conference PowerPoint presentations contained more recent data than publications, these were retrieved where possible. For time to event outcomes (overall survival, disease-free survival and recurrence), the following were recorded: (1) the number of events and/or proportions of women experiencing an event in each arm; and, (2) hazard ratios (HRs) and 95% confidence intervals.

Analysis

Overall survival is defined as the time from randomisation until death from any cause, and is measured in the intent to treat (ITT) population. Breast cancer-related survival was abstracted from papers as reported. The reader should be aware that definitions of this outcome differ subtly, for instance: "death after recurrence" does not necessarily mean the woman died of breast cancer; likewise, "death following cancer event", which may not necessarily be a breast cancer event; similarly "death: breast cancer-related" may mean either death with disease or death from disease; "deaths as a result of breast cancer" is more easily understood.

Disease-free survival (DFS) is usually defined as the time from randomisation until recurrence of tumour or death from any cause. Whether deaths occurring without prior documentation of disease recurrence should be scored as events or should be censored in the statistical analysis. Where deaths are censored, this is often called "time-to-recurrence" or simply "recurrence," but nomenclature is not a reliable guide to what is being measured: there is one trial included in the evidence review which has an outcome called "disease-free survival" where deaths without disease are censored.

It is worth noting that both disease-specific endpoints have their merits and demerits. Trial endpoints where death without disease is scored as an event are analysed as "disease-free survival" in this review. The Food and Drug Administration (FDA) states that this approach is less prone to bias, but: "Limitations of this approach are a potential decrease in statistical power of the study (by diluting the cancer-related events with deaths not related to cancer) and a potential to falsely prolong the disease-free survival estimates in patients who die after a long unobserved period. The latter could introduce bias if the frequency of long-term follow-up visits is dissimilar on the study arms or if there is nonrandom dropout due to toxicity."

Trial endpoints where deaths without disease have been censored are analysed as "breast cancer recurrence" in this review. The FDA states that: "This method has the potential for bias in the post hoc determination of the cause of death. Furthermore, any method that censors patients, whether at death or at the last visit, assumes that the censored patients have the same risk of recurrence as noncensored patients. This critical assumption needs close examination in any setting where deaths are to be censored. In settings where deaths due to causes other than cancer are common (e.g., studies of patients with early metastatic prostate cancer), censoring deaths can be appropriate." Researchers calculate "breast cancer recurrence" by adding together first events that are either loco-regional or distant recurrences, or new primary cancers in the contralateral breast. Death, with or without breast cancer, is not counted as an event in this outcome.

First events were recorded only when reporting loco-regional recurrences, distant recurrences and the occurrence of cancer in the contralateral breast. For the purposes of our analysis, "loco-regional recurrence" is defined as recurrence within the ipsilateral breast, chest wall, local lymph nodes, or skin at the surgical site. "Distant recurrence" is defined as recurrence at any other site apart from the contralateral breast. Where metastatic disease occurs simultaneously with a local or contralateral recurrence, researchers have treated metastatic disease as the first event. In each case, death does not count as an event.

The adverse events of interest are those associated with aromatase inhibitors (bone health, cardiovascular events, hypercholesterolemia), or tamoxifen (endometrial cancer and vaginal bleeding). They are recorded as reported in the primary studies, however defined.

Finally, health-related quality of life is recorded as reported, however defined.

The Absolute Risk Reduction (ARR) and Numbers Needed to Treat Benefit (NNTB) for time-to-event outcomes were calculated using a method that uses the

numbers of patients still at risk (alive) at the time corresponding to the estimated probabilities (reported or imputed), or hazard ratios and 95% confidence intervals, to calculate confidence intervals for each statistic.

Where baseline population characteristics, interventions, outcome definitions and follow-up periods were judged to be similar, the National Institute for Health and Clinical Excellence (NICE) requested researchers assess if there was any evidence to support a difference in treatment effect between aromatase inhibitors. In the absence of head-to-head comparisons, researchers use the method to compare two hazard ratios (with tamoxifen as a common comparator) using a test of interaction (or "indirect comparison").

Cost Effectiveness

Quality Assessment Strategy

The quality of studies was assessed using a combination of key components of the British Medical Journal checklist for economic evaluations together with the Eddy checklist on mathematical models employed in technology assessments.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and

the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

- The Assessment Group reviewed the literature and the submitted economic evidence, and generated its own economic model.
- Generally, treatment with aromatase inhibitors was associated with increased drug costs and slightly decreased follow-up costs (for example, the costs of treating disease recurrence) compared with tamoxifen. Adverse events made a very minor contribution to the costs.

See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

This guidance applies to the use of the aromatase inhibitors anastrozole, exemestane, and letrozole, within the marketing authorisations for each drug at the time of this appraisal, for the treatment of early oestrogen-receptor-positive breast cancer; that is:

- Anastrozole for primary adjuvant therapy
- Exemestane for adjuvant therapy following 2–3 years of adjuvant tamoxifen therapy
- Letrozole for primary adjuvant therapy and extended adjuvant therapy following standard tamoxifen therapy.

The aromatase inhibitors anastrozole, exemestane, and letrozole, within their licensed indications, are recommended as options for the adjuvant treatment of early oestrogen-receptor-positive invasive breast cancer in postmenopausal women.

The choice of treatment should be made after discussion between the responsible clinician and the woman about the risks and benefits of each option. Factors to consider when making the choice include whether the woman has received tamoxifen before, the licensed indications and side-effect profiles of the individual drugs and, in particular, the assessed risk of recurrence.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer in postmenopausal women

POTENTIAL HARMS

Because aromatase inhibitors reduce circulating oestrogen levels, a decrease in bone mineral density can be anticipated. Therefore, a warning has been included in the summaries of product characteristics of all three aromatase inhibitors that women with osteoporosis or at risk of osteoporosis should have their bone mineral density formally assessed by bone densitometry at the beginning of treatment and, for anastrozole, at regular intervals thereafter. Treatment or prophylaxis for osteoporosis should be initiated as appropriate and patients treated with an aromatase inhibitor should be carefully monitored.

Further side effects and contraindications are associated with individual aromatase inhibitors. For full details of side effects and contraindications, see the Summaries of Product Characteristics available at http://emc.medicines.org.uk/.

CONTRAINDICATIONS

CONTRAINDICATIONS

- Anastrozole is contraindicated in pre-menopausal women; pregnant or lactating women; people with severe renal disease; people with moderate or severe hepatic disease; people with known hypersensitivity to anastrozole or to any of its excipients (see marketing authorisation for further details); or, concomitant oestrogen-containing therapies.
- Letrozole is contraindicated in pre-menopausal women; hormone receptor status negative or unknown women (pre-operative use only); pregnant or lactating women; people with moderate or severe hepatic or renal impairment; people with hypersensitivity to the active substance or to any of its excipients (see marketing authorisation for further details).
- Exemestane is contraindicated in pre-menopausal, pregnant or lactating women and people with a known hypersensitivity to the active substance or to any of the excipients.

For full details of side effects and contraindications, see the Summaries of Product Characteristics available at http://emc.medicines.org.uk/.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The

guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organisations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 that requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (see "Implementation Tools" field). These are available on the following website: www.nice.org.uk/TA112.
    - Costing report and costing template to estimate the savings and costs associated with implementation.
    - Audit criteria to monitor local practice.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides
Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. 37 p. (Technology appraisal guidance; no. 112).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Nov

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Dr Jane Adam, Radiologist, St George's Hospital, London; Professor A E Ades, MRC Senior Scientist, MRC Health Services Research Collaboration, Department of Social Medicine, University of Bristol; Dr Tom Aslan, General Practitioner, Stockwell, London; Professor David Barnett (*Chair*) Professor of Clinical Pharmacology, University of Leicester; Mrs Elizabeth Brain, Lay member; Dr Karl Claxton, Health Economist, University of York; Dr Richard Cookson, Senior Lecturer in Health Economics, School of Medicine Health Policy and Practice, University of East Anglia; Mrs Fiona Duncan, Clinical Nurse Specialist, Anaesthetic Department, Blackpool Victoria Hospital, Blackpool; Professor Christopher Eccleston, Director, Pain Management Unit, University of Bath; Dr Paul Ewings, Statistician, Taunton & Somerset NHS Trust; Professor John Geddes, Professor of Epidemiological Psychiatry, University of Oxford; Mr John Goulston, Director of Finance, Barts and the London NHS Trust; Mr Adrian Griffin,

Health Outcomes Manager, Johnson & Johnson Medical; Ms Linda Hands, Consultant Surgeon, John Radcliffe Hospital; Dr Elizabeth Haxby, Lead Clinician in Clinical Risk Management, Royal Brompton Hospital; Dr Rowan Hillson, Consultant Physician, Diabeticare, The Hillingdon Hospital; Dr Catherine Jackson, Clinical Senior Lecturer in Primary Care Medicine, University of Dundee; Professor Richard Lilford, Professor of Clinical Epidemiology, Department of Public Health and Epidemiology, University of Birmingham; Dr Simon Mitchell, Consultant Neonatal Paediatrician, St Mary's Hospital, Manchester; Ms Judith Paget, Chief Executive, Caerphilly Local Health Board, Wales; Dr Katherine Payne, Health Economist, The North West Genetics Knowledge Park, The University of Manchester; Dr Ann Richardson, Independent Research Consultant; Dr Stephen Saltissi, Consultant Cardiologist, Royal Liverpool University Hospital; Mr Mike Spencer, General Manager, Clinical Support Services, Cardiff and Vale NHS Trust; Dr Debbie Stephenson, Head of HTA Strategy, Eli Lilly and Company; Professor Andrew Stevens (*Vice Chair*) Professor of Public Health, University of Birmingham; Dr Cathryn Thomas, General Practitioner, and Associate Professor, Department of Primary Care and General Practice, University of Birmingham; Simon Thomas, Consultant Physician, General Medicine and Clinical Pharmacology, Newcastle Hospitals NHS Trust; Dr Norman Vetter, Reader, Department of Epidemiology, Statistics and Public Health, College of Medicine, University of Wales, Cardiff; Professor Mary Watkins, Professor of Nursing, University of Plymouth; Dr Paul Watson, Medical Director, Essex Strategic Health Authority

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

- Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.
- A member of the School of Health and Related Research (ScHARR) staff, who is not part of the ScHARR Technology Assessment Group, has been involved in the development of a cost effectiveness model for letrozole. His involvement began before he joined ScHARR and has continued in a private (non-University) role. The individual has licensed his modelling work to a third party. The member of staff concerned has in no way been involved with the team responsible for the hormonal therapies for breast cancer assessment report.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. 2 p. (Technology appraisal 112). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.
- Costing template and report. Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. Various p. (Technology appraisal 112). Available in Portable Document Format (PDF) from the NICE Web site.
- Audit criteria. Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. 8 p. (Technology appraisal 112). Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N1150. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Hormonal therapies for the adjuvant treatment of early oestrogen-receptor-positive breast cancer. Understanding NICE guidance. Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2006 Nov. 5 p. (Technology appraisal 112).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1151. 11 Strand, London, WC2N 5HR.

NGC STATUS

This NGC summary was completed by ECRI on February 5, 2007.

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Date Modified: 9/29/2008


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